REMARKS

Upon entry of this amendment, Claims 1 and 5-11 constitute the pending claims in the present application. Among them, Claims 7 and 10 are directed to non-elected species, and are withdrawn from further consideration. Claims 2-4 and 12-17 are canceled without prejudice. Applicants reserve the right to prosecute claims of similar or identical scope in future divisional and/or continuation applications.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Rejections under 35 U.S.C. § 102

The Office Action rejects Claims 1, 5, 6, 8, 9, and 11 for allegedly being anticipated by WO 03/097011 A1 ("Barth") under 35 U.S.C. § 102(e). The Office Action alleges that Barth "discloses a method of treating gastroesophageal reflex disease (GERD) ... sleep disorders, sleep apnea and snoring..." The Office Action cited certain passages of Barth to support this contention.

Applicants have amended Claim 1 and its dependent Claims 5, 6, 8, 9, and 11 to clarify the subject matter claimed. Applicants submit that the amended claims are directed to the treatment of snoring, using an agent normally used for treating hyperacidity and GERD, in snoring patients who may or may not have GERD.

Applicants submit that Barth fails to disclose the treatment of snoring with the subject agents. The entire specification of Barth refers to "snoring" only once in page 8, the second full paragraph (line 14): "[i]n other embodiments, the invention provides methods for treating and preventing one or more symptoms associated with or caused by sleep apnea ... Physical signs that suggest obstructive sleep apnea syndrome or obstructive sleep apnea include loud snoring, witnessed apneic episodes, obesity, excessive daytime sleepiness, and nocturnal snorting and gasping" (emphasis added).

Applicants submit that in this context, Barth is merely suggesting that sleep apnea can be treated using certain proton pump inhibitors, and that by treating sleep apnea, some of its associated symptoms can also be alleviated. However, this disclosure does not teach that certain

"physical signs" that suggest the presence of sleep apnea, such as *obesity* or *loud snoring*, can be treated *directly* with those agents. In other words, if one were to conclude that Barth teaches the treatment of snoring with such agents, then one could just as well conclude that Barth also teaches the treatment of obesity with such agents.

In contrast, the presently claimed invention in respect to the treatment of snoring applies to all patients regardless of whether they happen to exhibit sleep apnea (just like a diabete drug applies to all diabetic patients regardless of whether they also happen to have sleep apnea). The prevalence of snoring is much greater than that of obstructive sleep apnea. In fact, the majority of patients with a snoring disorder do not have clinically detectable or significant sleep apnea. Barth never suggested treating snoring in this majority of snoring patients. In the minority of snoring patients who also happen to have sleep apnea, any benefit of Barth appears purely incidental and utterly unrealized.

Therefore, Barth does not anticipate the claimed invention. Reconsideration and withdrawal of this objection is respectfully requested.

The Office Action also rejects Claims 1, 5, 6, 8, 9, and 11 for allegedly being anticipated by U.S. Pat. No. 6,353,005 ("Rubin") under 35 U.S.C. § 102(a) and (e).

Applicants submit that Rubin relates to the treatment of gastro-intestinal disorders, including reflux and emesis. The entire specification of Rubin fails to mention "snoring" or "sleep disordered breathing" even once. The Office Action admits that Rubin does not explicitly teach the treatment of sleep disorders, sleep apnea and snoring. However, the Office Action argues that at least one proton pump inhibitor "such as lansoprazole (a.k.a. PREVACID), would have inherently treated sleep disorders, sleep apnea and snoring, since said chemical composition comprising lansoprazole and its properties are inseparable." Applicants respectfully disagree.

Pursuant to MPEP 2112, "[t]he fact that a certain results or characteristics may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)" (emphasis in original). The prior art method at best teaches the treatment of GERD patients, who may or may not have snoring problem. Simply because the prior art teaches the use of certain proton pump inhibitors to

treat GERD patients, only *some* of which happen to have snoring problem, does not necessarily mean that the prior art also inherently teaches the use of such inhibitors to treat snoring. If this were the case, the prior art could be said to have inherently taught the use of such inhibitors for treating *any* condition, so long as such condition may have occurred in a GERD patient.

To support its argument, the Office Action also cites several cases, such as *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999), *In re Best*, 195 USPQ 430, 433 (CCPA 1977), and *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). However, Applicants here are claiming a new method of using an old composition, not the old composition itself. Therefore, the holdings of these cases do not apply to the instant claims.

Thus, Rubin cannot anticipate the amended claims. Reconsideration and withdrawal of this objection is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

The Office Action rejects Claims 1, 5, 6, 8, 9, and 11 for allegedly being obvious over WO 03/053221 A2 ("Ieni"), in view of either Senior *et al.* ("Senior") or Xiao *et al.* ("Xiao").

As argued above, Applicants have amended independent Claim 1 and its dependent claims to clarify the subject matter claimed.

Applicants submit that both Senior and Xiao relate to treating patients with GERD and patients with obstructive sleep apnea syndrome (OSAS). There is not any reference to snoring in either Senior or Xiao.

Ieni relates to the treatment of GERD. Again, there is no reference to snoring.

Therefore, even assuming, for the sake of argument, that a skilled artisan is motivated to combine Ieni with either Senior or Xiao, the combined teaching still fails to teach all the limitations of the claimed invention. Thus at least one of the three requirements for establishing a *prima facie* case of obviousness has not been met. Reconsideration and withdrawal of this objection is respectfully requested.

Claims 7 and 10 are directed to non-elected species, and are thus presently withdrawn from further consideration. However, if the linking claim 6, which encompasses the elected and non-elected species, is found to be allowable, Applicants respectfully request the Examiner to withdraw the Restriction Requirement and rejoin Claims 7 and 10.

CONCLUSION

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. The Director is hereby authorized to charge any other deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. **18-1945**, under Order No. **SOHN-P01-001**.

Dated: August 2, 2006

Respectfully submitted,

By_____

Yu Lu, Ph.D., J.D.
Registration No.: 50,306
Fish & Neave IP Group
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant